

Serial No.: 10/075,970

REMARKS

Status of the claims

Claims 1, 3, 5-7, 9-21, 46 and 47 are pending in the application.

Support for amendments

Support for new claims 46 and 47 can be found, for example, in the original specification at paragraphs [0069] and [0070]. No new matter is added.

Rejection over Eury and Bolz

Claims 1, 3, 5, 6 and 9-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Eury US 5,443,458 in view of Bolz et al. US 6,287,332 (Bolz). This rejection and its accompanying remarks are respectfully traversed.

The medical devices recited by the instant claims have a biodegradable inner core material and a biodegradable covering material. The inner core is selected from a metallic material and a ceramic material. A key concept of the present claims is that the covering material substantially controls the rate at which the inner core material becomes flexible upon contact with bodily fluids, wherein after insertion or implantation into a patient, the medical device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. *Ex parte Rubin*, 5 U.S.P.Q. 2d, 1461 (BPAI 1987).

In Eury, however, the laminated outer layers are drug releasing layers. There is no teaching or suggestion in Eury that these layers are to be provided with characteristics (e.g., a sufficient thickness) that would allow these layers to substantially control the rate at which the inner core material becomes flexible upon contact with bodily fluids as claimed. In other words a critical concept of applicant's claimed invention is not disclosed.

Bolz, which is cited for teaching of degradable metallic materials for coronary stents, does not make up for the deficiencies in Eury.

There is also recited a specific range of time in which to become completely biodegradable and to remain sufficiently rigid to serve their purpose in new claims 46 and 47. Nothing in Eury or Bolz suggests those time ranges.

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Nor does any disclosure in Eury or Bolz suggest, for example, an inner core material comprising a ceramic core as claimed in claim 10, a monofilament core or a multifilament core as claimed in claims 11-13, or an additional coating layer, which may contain at least one therapeutic agent as claimed in claims 17 and 18.

Although the Examiner has referred to Litner, that reference was not cited in the statement of the rejection. "Where a reference is relied on to support a rejection, whether or not in a minor capacity, it should be positively included in the statement of the rejection." MPEP 706.02(j), citing *In re Hoch*, 438 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (Fed. Cir. 1970). See also MPEP Sects. 1208.01 and 2144.08.

In view of the above, it is respectfully submitted that the combination of references relied on fails to support a *prima facie* case of obviousness. *In re Jones*, 958 F.2d 347, 351, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992), *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 1596, 1598-99 (Fed. Cir. 1988).

Reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are respectfully requested.

Rejection over Eury, Bolz and Langer

Claim 7 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Eury in view of Bolz and Langer et al. US 6,160,084 (Langer). This rejection and its accompanying remarks are respectfully traversed.

The deficiencies in Eury and Bolz with respect to claim 1 (from which claim 7 indirectly depends) are discussed above. Langer does not make up for those deficiencies. Langer discloses the use of shape memory polymers in articles such as car bumpers and "biomedical devices which can form a second shape upon reaching at (sic) body temperature, or upon application of an external stimulus which heats the device above body temperature." See column 13, lines 12-25. Moreover, the present claims relate to changes in "rigidity" over time.

Reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are respectfully requested.

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CONCLUSION

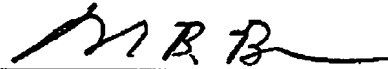
Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,

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